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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/869,796 | 09/19/2001 | Eric DeFranco | 110024 | 1327 |
| 25944 | 7590 | 04/06/2004 | EXAMINER | |
| OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320 | | | LEWIS, PATRICK T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
| DATE MAILED: 04/06/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------|-----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/869,796 | DEFRANCO ET AL. | |
| | Examiner | Art Unit | |
| | Patrick T. Lewis | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Response dated October 15, 2003

1. In the Response filed October 15, 2003, claims 6, 13, 18, and 23 were amended; claim 28 was added. Applicant presented arguments directed to the rejection of claims 1-27 under 35 U.S.C. 112, second paragraph. Claims 1-28 are pending. An action on the merits of claims 1-28 is contained herein below.
2. The objection to claim 23 has been rendered moot in view of applicant's amendment dated October 15, 2003.
3. The rejection of claims 1-27 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record as set forth in the Office Action dated July 15, 2003.

Objections/Rejections of Record Set For the in Office Action dated July 15, 2003

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims reading upon a compound of general formula (I), (I'), or (II) are indefinite. The attachment of the linker **L** to the nucleotide **W** has not been properly defined. In the absence of a recitation of the specific atoms participating in the chemical bond between

L and **W**, all claims reading upon said formulae are indefinite as one of ordinary skill in the art at the time of the invention would not be apprised of the metes and bounds of the instant invention.

The term "nucleotide analog" renders all claims reading upon said term indefinite. In the absence of distinct modifications to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of modified compounds of this invention, the identity of said analogs would be difficult to describe and the metes and bounds of said analogs applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

The term **L** has not been sufficiently defined. **L** is described as "comprising at least four atom". No atoms are identified. Furthermore, the language is open-ended meaning any combination of atoms, arranged in any manner, reads upon **L**. The specific atoms applicant intends to read upon **L** along with their arrangement/connectivity is required to apprise one of ordinary skill in the art of the metes and bounds of the instant invention.

7. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). Claims 9 and 21 depend ultimately from independent claims 1 and 13,

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respectively. Claims 1 and 13 read upon a nucleotide and polynucleotide, respectively. The compounds of claims 9 and 21 do not read upon either. A nucleotide must have a phosphate attached at the 2', 3', or 5' position.

8. Applicant's arguments filed October 15, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) it would have been understood by one of ordinary skill in the art that compounds having the claimed structure, regardless of the atom of nucleotide analog W to which the linker L is attached, are within the present claims; 2) the fact that the phrase "comprising at least four atoms" is open-ended does not render the term L indefinite, as one of ordinary skill in the art can clearly recognize a chemical structure that comprises at least four atoms; and 3) the fact that the term "nucleotide analog" does not specifically recite all of the modifications encompassed by the term does not render the term indefinite.

The examiner disagrees with applicant's assertions. The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. In the instant case, the variable L reads upon an infinite number of atoms, arranged/attached in an infinite number of ways. In turn, this moiety represented by the variable L is attached to a variable W that is defined as a "nucleotide analog". In the absence of distinct modifications to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of analogs of this invention, the identity of said analogs would be difficult to describe and the metes and bounds of

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said analogs applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. The examiner acknowledges the cited passage in the instant disclosure wherein applicant describes the term "nucleotide analog". However, although it is proper to use the specification to interpret what is meant by a word or phrase in a claim, this is not to be confused with adding an extraneous limitation appearing in by not required by the specification, which is improper. Additionally, the term "nucleotide analog" as described by applicant does not conform to the conventional definition of a "nucleotide" which requires phosphorous-containing moiety at the 2', 3', or 5'-position. For the forgoing reasons, claims reading upon the instantly claimed compounds of general formula (I), (I'), or (II) and methods employing said compounds are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims reading upon a compound of general formula (I) are indefinite. The attachment of the linker **L** to the nucleotide **W** has not been properly defined. In the

absence of a recitation of the specific atoms participating in the chemical bond between **L** and **W**, all claims reading upon said formulae are indefinite as one of ordinary skill in the art at the time of the invention would not be apprised of the metes and bounds of the instant invention.

The term "nucleotide analog" renders all claims reading upon said term indefinite. In the absence of distinct modifications to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of modified compounds of this invention, the identity of said analogs would be difficult to describe and the metes and bounds of said analogs applicant regards as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

The term **L** has not been sufficiently defined. **L** is described as "comprising at least four atom". No atoms are identified. Furthermore, the language is open-ended meaning any combination of atoms, arranged in any manner, reads upon **L**. The specific atoms applicant intends to read upon **L** along with their arrangement/connectivity is required to apprise one of ordinary skill in the art of the metes and bounds of the instant invention.

Conclusion

11. Claims 1-28 are pending. Claims 1-28 are rejected. No claims are allowed.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

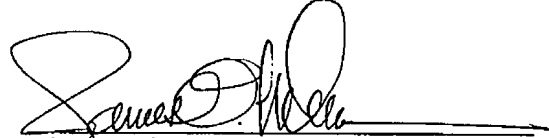
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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January 12, 2004